Securing Multidisciplinary Support & Multimodality Studies

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Agenda

- Background
- Themes & Considerations
- Previous Experience/Examples
- Panel Discussion
- Questions

Background: Definition

Multi-modality: more than 1 research intervention (e.g. chemo, surgery, or radiation, diagnostic, psychosocial)

Multi-disciplinary: draws from medical specialists from different disciplines (e.g., pathologists, radiologists, surgeons, etc)

YOUR TURN!

IN THE CHAT, ARE ALL MULTIMODALITY TRIALS CONSIDERED MULTIDISCIPLIANRY?

- Yes
- No

YES
However, not all multidisciplinary trials are considered multimodality

Themes & Considerations

Design Considerations

- Generating hypotheses
- Defining Endpoints
- Establishing Eligibility
- Logistics
- Data Collection
- Clinical Workflows

Responsibilities

- Communicating/Avoiding conflicts
- Determining roles: PI versus Co-PI
- Obtaining Support; key stakeholders
- Identifying Patients
- Assessing Toxicities
- Cost
- Authorship

Previous Experience/ Examples

Experiences & Examples

IRB# 19-272

- **PI:** Medicine, Co-PI: Surgery
- **Title:** Feasibility and Safety of Neoadjuvant Nivolumab and Chemotherapy for Resectable Malignant Pleural Mesothelioma

IRB# 20-104

- **PI:** Surgery, Co-PI: Medicine
- **Title**: A Phase II Study of Concurrent Systemic Pembrolizumab and Isolated Limb Infusion (ILI) with Melphalan and Dactinomycin for Patients with Locally Advanced or Metastatic Extremity Sarcoma

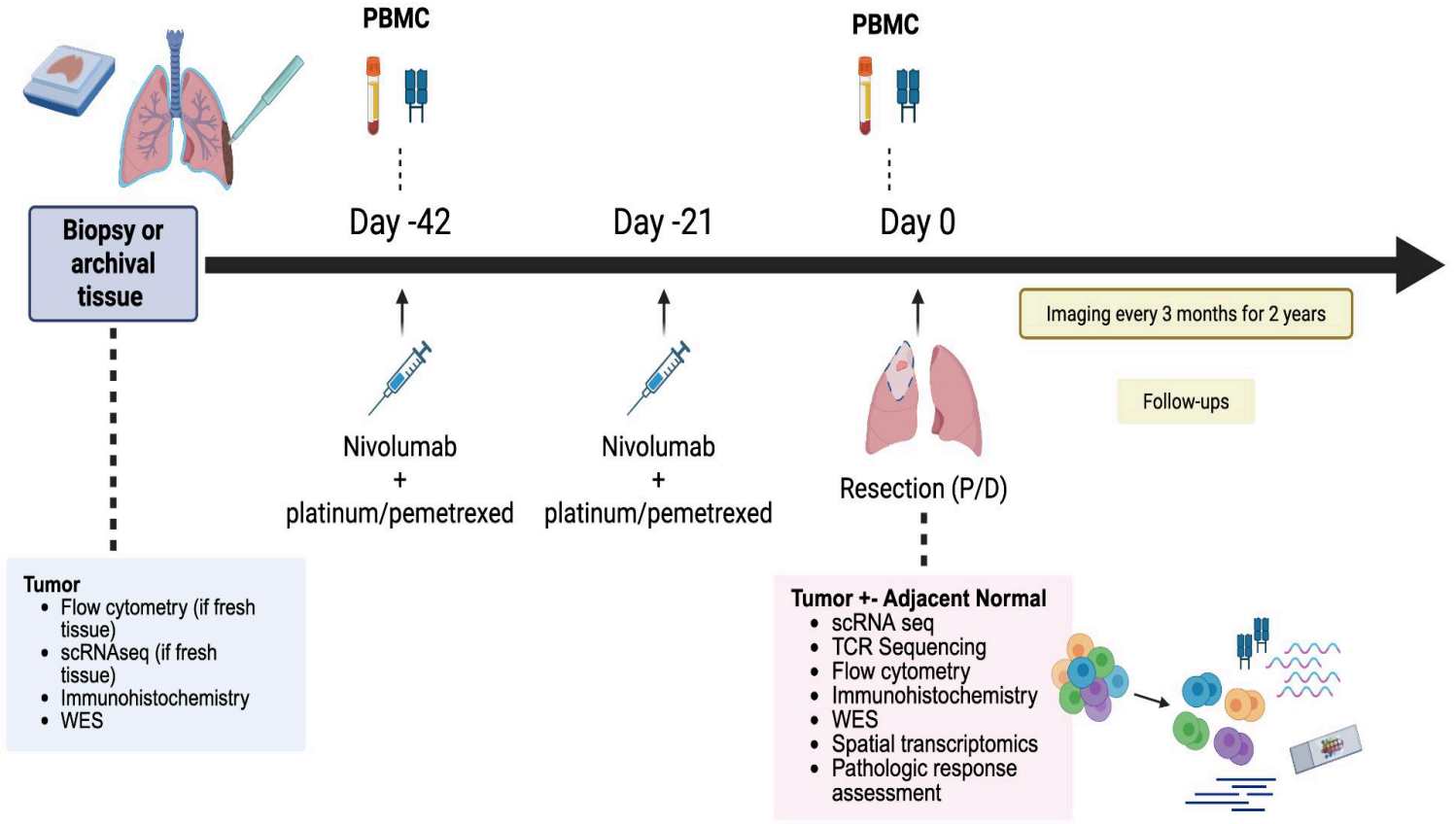
RADONC25-008

- **PI**: Radiation Oncology, Co-PI: Surgery
- **Title**: Alternative Boost Approaches in Radiation Therapy IRreversible Electroporation versus RADIAtioN BoosT for Intermediate Risk Prostate Cancer (IRRADIANT)

IRB# 19-272
PI: Offin

- **Key Inclusion Criteria:**
  - Operable/Resectable
  - KPS ≥70%
  - Platinum/pemetrexed/ICI naïve
- **Primary Objective**:
  - Attempted P/D within 30 days of the planned surgery date
- **Secondary Objective**:
  - Safety
  - Overall Survival (OS) from treatment start
  - Progression Free Survival (PFS)

Schema

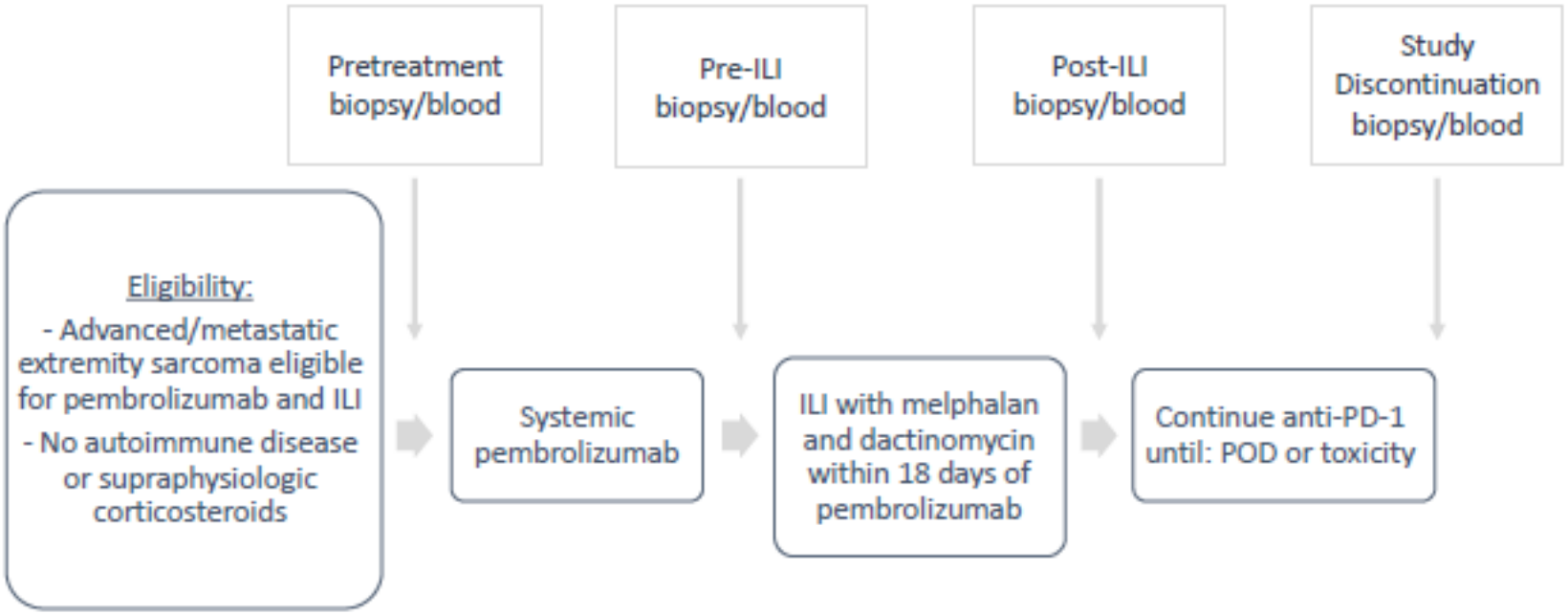


IRB# 20-104 (PI: Bartlett)

Study Schema

- Single-institution, single arm, phase II study
- Target accrual:
  30 patients
- Treatment:
  Systemic pembrolizumab administration every 3 weeks for up to 1 year

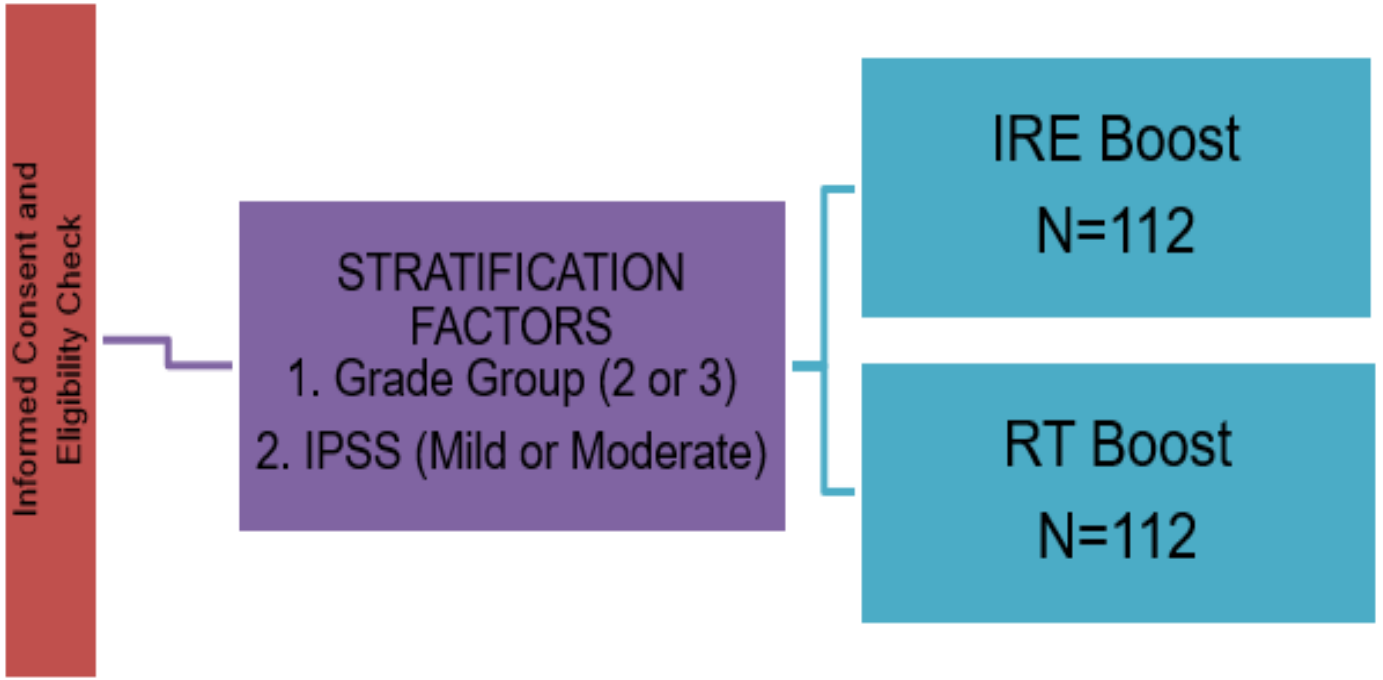
  ILI to affected extremity within 18 days of initiation of pembrolizumab



RADONC25-008
PI: Nagar

- **Key Inclusion Criteria:**
  - Biopsy proven grade group 2 or 3 (GS 3+4 or GS 4+3) cancer with all pattern 4 found only in the MRI target
- **Primary Objective**:
  - Demonstrate that IRE boost has a non-inferior negative biopsy rate at 2 years compared to RT boost .
- **Secondary Objective**:
  - bPFS, MFS, OS
  - Patient Reported Outcomes (PROs)
- **Exploratory Objectives** :
  - Correlative studies (tissue, serum, plasma, whole blood and urine)

Schema



Panel Discussion

Getting Started…Collaboration

- When should you start collaborating with other departments (e.g., pathology) or DMTs?
- How do you identify potential collaborators and engage outside groups?
- What groups do you consider and when?
- Why is buy-in critical to your trial's success?

Unique Considerations?

- What considerations are unique for multi-modality studies when generating your hypothesis and defining your trial endpoints?

- How does MSK compare to other institutions as a place to implement and conduct multidisciplinary trials?

Who is Responsible for What?

- What key responsibilities between modalities should be identified when designing your trial? (e.g., PI vs Co-PI, toxicity assessment, cost/funding, grants, authorship)

- At what stage in the collaboration should these responsibilities be discussed?

- How do multiple departments (e.g., pathology, medicine, surgery) coordinate research on biospecimens from studies given that this is a limited resource?

Communication & Engagement?

- What types of platforms work best to start lines of communication? e.g., individual emails, group emails, face-to-face, etc?

- How do you maintain engagement with other disciplines throughout the conduct of your study?

- In setting up collaborators, do you find regular meetings to be better?

Lessons Learned?

- What are some of the major lessons that you have learned from your experience designing and implementing multi-modality trials and/or collaborating with multiple disciplines?

Questions?